



CLINICAL EVALUATION OF VIJAYADI YOGA IN THE MANAGEMENT OF MADHUMEHA WSR TO DIABETES MELLITUS (TYPE-II)

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ABSTRACT

Madhumeha is a lifestyle disorder throughout the world. The disease *madhumeha* appears to have great similarity with diabetes mellitus hence *madhumeha* can be equated with diabetes mellitus. Recent research for global prevalence of diabetes by WHO concluded that the total number of people with diabetes is projected to raise from 171 million in 2000 to 366 million in 2036, keeping in view of this alarmingly increasing incidence. Research on *Vijayadi yoga* a herbo-mineral drug is conducted in the present study to assess its efficacy in the management of *madhumeha* (DM type II). 30 patients of *madhumeha* were selected from OPD and IPD of Kayachikitsa department from Dr.BRKR GAMC, Hyderabad, and were subjected to *Vijayadi yoga* 2 tabs of 500mg each TID before food with follow up at every 30days for 90 days. The results were assessed in terms of symptomatic relief and also laboratory investigations(FBS,PPBS,HbA1C). Statistically highly significant improvement was observed with P-value < 0.001. Hence the study revealed that the *Vijayadi yoga* is an effective drug in the management of *madhumeha* (Type II DM).

KEY WORDS: Madhumeha, DM type II, Vijayadi yoga, FBS, PPBS, HbA1C.

INTRODUCTION:

Madhumeha is a lifestyle disorder throughout the world. It is a disease as old as humanity; has a long and fascinating history. The disease *Madhumeha* is clearly mentioned as a type of *Prameha* in all *Samhitas* like *Charaka*¹, *Sushruta*², & *Ashtanga Hridayam*³. One of the symptom of *Madhumeha* explained in *Ashtanga Hridayam Nidana* is “*Madhumehi Madhu Samam Mutram*”⁴ which means honey like sweet urine, this can be correlated to glycosuria. The disease *Madhumeha*, its definition, etiology, clinical picture & principles of treatment appears to have great similarity with diabetes mellitus. Hence, *Madhumeha* can be equated with diabetes mellitus.

Type-II Diabetes Mellitus is a group of metabolic disorder which is characterized by hyperglycemia & insulin resistance, which may be combined with relatively reduced insulin secretion⁵. It is mainly produced by variations in life style, like faulty dietary habits, lack of exercise, tension; addictions like smoking & alcoholism etc of modern men. Modern science considered diabetes mellitus as a metabolic disorder but the latest evidence based facts illustrates that genetic, environmental, functional, hereditary & mental factors also contribute in the production of disease. It is such a disease which has become a lifestyle disorder & the number of people with diabetes mellitus type- II is increasing day by day due to population growth, aging, urbanization, increasing prevalence of obesity & physical inactivity.

The recent research for global prevalence of Diabetes by WHO concluded that, the total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030⁶. India is included in the top 3 countries having highest number of people with diabetes along with China & U.S. The urban population in developing countries is projected to double during 2000 to 2030 & prevalence in rural area is estimated to be half of urban area.

Incidence rate in India: Hyderabad-16.7 %; Chennai-13.5 %; Bangalore-12.4 %; Kolkatta-11.7%; New delhi-11.6%; Mumbai 9.3%⁷.

In spite of this much high rates of increasing prevalence in all over the world & tremendous advancement of modern system of medicine i.e. oral anti-hyperglycemic agents & insulin, an ideal drug which can cure Diabetes is not yet available but still scientist are struggling to search an effective and harmless therapy.

- ⚡ The impacts of Type-II Diabetes Mellitus are considerable as a lifelong disease; it increases morbidity, mortality & decreases the quality of life.
- ⚡ At the same time, the disease & its complications cause a heavy economic burden for diabetic patients themselves, their families & society.
- *Ayurveda* has described that it is not rational treatment where medicine modifies one disease & on the other hand it provokes new complains. So effort has been made here to search the safe & effective medicine, without any side effect.

- Therefore in the present study sincere effort is made to decrease the dose of anti-hyperglycemic drugs & complication of Diabetes mellitus by improving the quality of life.

Moderate infrastructure was provided by DR. B.R.K.R. Govt. Ayurvedic College. A minimum of 30 patients were randomly selected from OPD & IPD of Dr. B.R.K.R Government Ayurvedic College & hospital, Hyderabad. Sample size is fulfilled.

Aims and Objectives Of Study

- To access the efficacy of *Vijayadi Yoga* in the management of *Madhumeha* w.s.r. to Diabetes mellitus (Type-II) in 30 patients.
- To enhance the quality of life in Diabetics

MATERIAL & METHODS :

A. Materials

The present clinical study on *Madhumeha* was designed as follows:

- ❖ Source Of Data
30 patients of *Madhumeha* are selected irrespective of sex, diet, occupation & religion between age group of 25 to 65 years from O.P.D., I.P.D., & cases referred by other department of Dr B.R.K.R. Govt. Ayurvedic Medical College & Hospital, Hyderabad.
- ❖ Criteria For Selection Of The Patient
 - Inclusive criteria
 1. Subjects presenting with clinical features of Madhumeha (NIDDM).
 2. Patients of Type-II diabetes mellitus having FBS up to 250mg/dl and PPBS up to 300mg/dl.
 3. Subjects of either sex between age group of 25 – 65 years.
 4. Cases of diabetes mellitus within 5 years of detection.
 - Exclusive criteria
 1. Subjects of Sahaja Madhumeha (IDDM)
 2. Subjects with severe diabetic complications like retinopathy, nephropathy & neuropathy etc.
 3. Diabetes mellitus due to other hormonal disturbances like Phaeochromocytoma, Acromegaly, Thyrotoxicosis etc.
 4. Pregnant women (Gestational DM)
 5. Diabetes due to side effects of drugs like Diuretics (Thiazide groups), Steroids.

6. Diabetes with any other systemic and metabolic disorders like varicosity, venous ulcers.

❖ Diagnostic criteria

1. Subjects will be diagnosed as per the clinical features of Madhumeha (NIDDM).

2. Subjects with FBS more than 120 mg/dl and PPBS more than 180mg/dl.

❖ Investigations

❖ Routine hematological examination & other investigations if required before treatment to rule out any other pathological conditions.

❖ HbA1c level (before treatment & after follow up)

❖ F.B.S., P.P.B.S. (before & after treatment).

B. Methodology:

❖ **Study Design:** The present study is an open clinical trial. Informed consent was taken from all the patients before including them in the trial.

❖ **Sample Size:** Total 30 patients are randomly selected.

❖ **Study Plan:**

• A special case Proforma was designed which consists of all the important data related to patients of *Madhumeha*, treatment adopted & other information.

• Standard scorings were given for the subjective as well as objective parameters for the assessment before & after treatment.

• The study was done in single group.

• All the 30 patients were administered *Vijayadi Yogam 500mg tablets 2 TID*. The treatment was planned for 90 days with three follow ups, each on 30th, 60th and 90th day.

• For fresh cases drug started immediately after the diagnosis confirmed.

• For the patients who are already using oral anti-hyperglycemic drug are advised to withdraw 1/4th of the drug before starting the trail drug.

• The patients are observed carefully in 1st cycle & gap period, if they are comfortable with the drug & dosage & sugar levels are maintained well they are advised to withdraw another 1/4th in next cycle.

❖ **Trial Drug:**

Drug selected for the present study is "*Vijayadi Yoga*"

Materials For *Vijayadi Yoga*

1) Vijaya saara churna	}	Churna Dravyas
2) Haridra churna		
3) Methika churna		
4) Jambu beeja churna		
5) Karavellaka churna		
6) Trivanga bhasma	}	Bhavana Dravyas
7) Haridra swarasa		
8) Karela swarasa		
9) Amalaki swarasa		

Method of Preparation of Vijayadi Yoga-

All the churnas are mixed together homogenously & than vatis of size 500 mg are prepared by giving 3 bhavanas each of haridra swarasa, karela swarasa and amalaki swarasa

Table 1 – Pharmacological Property of Drugs of VIJAYADI YOGA^{8,9}
10,11,12,13,14,15,16

Name	Rasa	Guna	Virya	Vipaka	Doshaghnata
Vijaya Saar	Kashaya, Tikta.	Laghu, Ruksha	Sita	Katu	Kapha, Pitta Shamaka
Haridra	Tikta, Katu	Laghu, Ruksha	Ushna	Katu	Kapha, Vata Shamaka
Methika	Katu, Tikta	Laghu, Snigdha,	Ushna	Katu	Vata Kapha Shamaka
Jambu	Madhura, Kashaya, Amla	Laghu, Ruksha,	Sita	Katu	Vata Vardhaka, Kapha Pitta Shamaka
Karavellaka	Tikta, Katu	Laghu, Ruksha	Sita	Katu	Pitta, Kapha Shamaka
Trivanga Bhasma	Katu, Tikta	Laghu, Snigdha	Usna	Katu	Vata, Kapha
Amalaki	Amla pradhana pancha rasa (Except lavana)	Laghu, Snigdha	Sita	Madhura	Tridosha

Dose:

2 Tabs TID 20 minutes Before Food.

Duration of Study

Total duration of study was 90 days with 3 follow ups each on 30th, 60th and 90th day.

Method of Assessment of Treatment

- The effect of the therapy was assessed pertaining to improvement recorded in clinical findings.
- Changes observed in signs & symptoms were assessed by adopting suitable scoring methods & objective signs by using appropriate clinical tools.
- Both subjective & objective assessments were done in all the patients before & after treatment. HbA1c level was done in all patient before treatment & after follow up period.
- Separate grading has been given for subjective assessment parameters that include the following.

1) Ati Mutrata 2) Ati Pipasa 3) Ati kshudha 4) Dourbalya

Above symptoms score was adopted depending upon severity for the assessment.

Assessment of Subjective Parameters:

Table 2 – Grading According severity of Symptoms¹⁷

Grade	Symptoms
0	Complete Relief or no symptom
1	Presence of mild symptoms
2	Presence of moderate symptoms
3	Presence of severe symptoms

(1) *Ati Mutrata* [Polyuria]

Table 3 – Grading Of *Ati Mutrata*

Grade	Frequency in day	Frequency in night	Volume
0	3-4	0-1	Normal
1	5-7	1-2	Excessive
2	8-10	2-3	Excessive
3	>10	3-4	Excessive

(2) *Ati Pipasa* [Polydipsia]

Table 4 – Grading Of *Ati Pipasa*

Grade	Feeling of thirst	Water intake
0	Normal	1.5 – 2 Liters
1	Increased : Frequency is more but volume intake can be controlled	2 – 2.5 Liters
2	Increased : High frequency (nearly once in 2 hours) and in good volume	2.5 – 3 Liters
3	Increased : High frequency and Excessive volume	> 3 Liters

(3) *Ati Kshudha* [Polyphagia]

Table 5 – Grading Of *Ati Kshudha*

Grade	No of Main meals	Quantity
0	2	Normal
1	3	Slightly Increased
2	4	Moderately Increased
3	>4	Markedly Increased

(4) *Dourbalya* [Weakness]

Table 5 – Grading Of *Dourbalya*

Grade	Routine activity & Weakness
0	Normal without feeling weakness
1	Normal with Slight feeling of weakness
2	Disturbed with moderate weakness
3	Disturbed with severe weakness

Assessment of Objective Parameters

FBS & PPBS

Table 6 – Range Of Blood Sugar Level¹⁰⁴

	Normal	Impaired Glucose Metabolism	Diabetic
FBS	<110 mg/dl	110-125mg/dl	≥126 mg/dl
PPBS	<140 mg/dl	140-199 mg/dl	≥200 mg/dl

HbA1c level

Table 7 – Range Of HbA1c Level

	Normal	impaired glucose metabolism	Good control	Weak control	Poor control
HbA1c	<5.7	5.7-6.4	6.5-7	7-8	>8

Overall Effect of Therapy:

Total effect of the therapy was assessed considering overall improvement in Subjective as well as objective parameters. After the treatment the total effect was recorded in following categories:

Table 8 – Effect of Therapy¹⁸

Effect	Percentage
Complete remission	100%
Marked relief	76-99%
Moderate relief	51-75%
Mild relief	26-50%
No relief	<25%

OBSERVATIONS AND RESULTS:

Table 9 – Mean FBS before & after treatment

Before treatment	After treatment
130.3	103.53

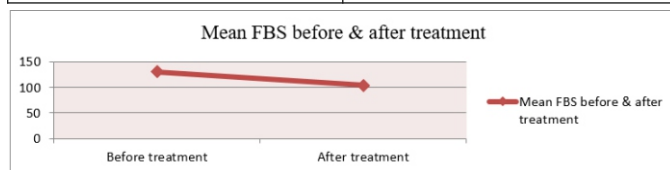


Table 10 – Mean PPBS before & after treatment

Before treatment	After treatment
233.03	173.6

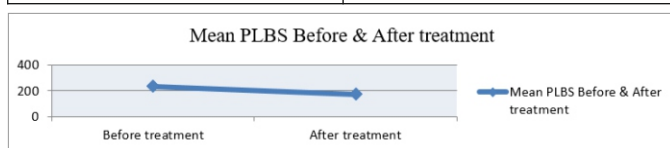


Table 11 – Mean HbA1c level before & after treatment

Before treatment	After treatment
7.90	6.68

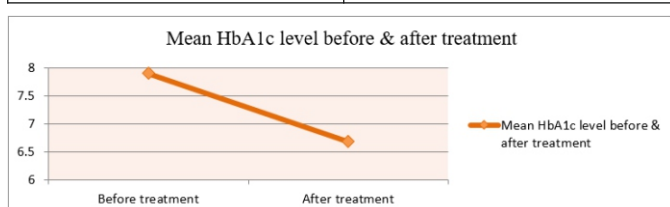


Table 12 – Overall response to therapy

Response	Patients	Percentage
Complete (100%)	0	0
Marked (76-99%)	10	33.33
Moderate (51-75)	18	60
Mild (25-50)	2	6.66
No (<25)	0	0

Overall response to therapy



Subjective Parameters:

Table 13 - Showing the results of *Ati Mutrata*

Grade	Before treatment		After treatment	
	No. Of patient	Percentage	No. Of patient	Percentage
Grade0	0	0	6	20
Grade1	1	3.33	24	80
Grade2	17	56.66	0	0
Grade3	12	40	0	0

Table 14 - Showing the results of *Ati Pipasa*

Grade	Before treatment		After treatment	
	No. Of patient	Percentage	No. Of patient	Percentage
Grade0	0	0	5	16.66
Grade1	2	6.66	23	66.66
Grade2	19	63.33	2	6.66
Grade3	9	30	0	0

Table 15 - Showing the results of *Ati Kshuda*

Grade	Before treatment		After treatment	
	No. Of patient	Percentage	No. Of patient	Percentage
Grade0	1	3.33	19	63.33
Grade1	9	30	11	36.66
Grade2	20	66.66	0	0
Grade3	0	0	0	0

Table 16 - Showing the results of *Dourbalya*

Grade	Before treatment		After treatment	
	No. Of patient	Percentage	No. Of patient	Percentage
Grade0	0	0	15	50
Grade1	2	6.66	14	46.66
Grade2	19	63.33	1	3.33
Grade3	9	30	0	0

Objective Parameters:

Table 17 - Showing the results of FBS

	Before treatment		After treatment	
	No. Of patient	Percentage	No. Of patient	Percentage
Normal (<110 mg/dl)	8	26.66	20	66.66
Impaired blood glucose metabolism (110-125mg/dl)	6	20	10	33.33
Diabetic (≥126 mg/dl)	16	53.33	0	0

Table 18 - Showing the results of PPBS

	Before treatment		After treatment	
	No. Of patient	Percentage	No. Of patient	Percentage
Normal (<140 mg/dl)	0	0	1	3.33
Impaired blood glucose metabolism (140-199mg/dl)	6	20	27	90
Diabetic (≥200 mg/dl)	24	80	2	6.66

Table 19 - Showing the results of HbA1c level

	Before treatment		After treatment	
	No. Of patient	Percentage	No. Of patient	Percentage
Normal (<5.7)	0	0	1	3.33
Impaired blood glucose metabolism (5.7-6.4)	1	3.33	7	23.33
Diabetic (good control) (6.5 - 7)	5	16.66	18	60
Diabetic (weak control) (7.1-8)	15	50	4	13.33
Diabetic (poor control) (>8)	9	30	0	0

STATISTICS:

Table 20 – Statistics of Subjective Parameters^{19,20,21,22,23,24}

S. n.	Lakshana	Mean		% of relief	S.D.		S.E.		t-value	p-value	S
		BT	AT		BT	AT	BT	AT			
1	Ati Mutrata	2.36	0.83	64.78	0.55	0.53	0.103	0.098	10.989	<0.0001	E.S.
2	Ati Pipasa	2.23	0.9	59.70	0.56	0.48	0.105	0.089	9.811	<0.0001	E.S.
3	Ati Kshudha	1.63	0.36	77.55	0.55	0.49	0.103	0.091	9.359	<0.0001	E.S.
4	Dourbalya	2.23	0.53	76.11	0.56	0.57	0.105	0.106	11.554	<0.0001	E.S.

Table 21 – Statistics of Objective Parameters^{19,20,21,22,23,24}

S. n.	Lakshana	Mean		% of change	S.D.		S.E.		t-value	p-value	S
		BT	AT		BT	AT	BT	AT			
1	FBS	130.3	103.53	20.54	28.30	9.37	5.25	1.74	4.91	<.0001	E.S.
2	PPBS	233.03	173.6	25.5	29.82	21.05	5.53	3.90	8.91	<.0001	E.S.
3	HbA1c	7.9	6.68	15.44	1.016	0.55	0.18	0.10	5.78	<.0001	E.S.

Degree of freedom = 29

Abbreviations :

S.D = Standard deviation, S.E = Standard error, S = level of Significance, E.S = Extremely Statistically Significant.

PROBABLE MECHANISM OF ACTION:

According to modern medical science, the mechanism of action of the drug may be one of these

- By decreasing absorption of glucose from the gut.
- By increasing peripheral utilization of glucose.
- By stimulating Beta cells to produce more insulin.
- By promoting insulin glucose production.
- The drug may be acting through one or more of the mechanism mentioned above.
- The precise mechanism is yet to be searched out & studied.

CONCLUSION:

On completion of this study, final conclusion drawn on the basis of deductive reasoning of data obtained from this clinical trial is as follows

- *Madhumeha* is considered as diabetes mellitus type-II in the present study. It is a metabolic disorder involving *dhatvagnimandhya*.
- *Madhumeha* is more prevalent in 45-55 years, in person with *vatakapha prakrati* & in people having mixed diet.
- *Ashyasukha* & *swapnasukha* were observed in most of the cases.
- *Dadhisevana* is one of the common ahatic *nidana* was observed in 60% of the cases & stress being common viharic *nidana* observed in 75% of cases.
- Shedding light on the symptomatology of the disease on the basis of *Ayurvedic* fundamentals it is evident that *Vata Kapha Dosha* is the chief culprit along with vitiation of *Pitta Dosha*. The vitiation of *Tridosha* is accompanied by vitiation of *Agni* which, in turn leads to *Rasa & Medodhatu*

Dushti predominantly. In the present trial, *Vijayadi Yoga* was found more effective.

- The present study by *Vijayadi Yoga* showed extremely statistically significant results ($P<0.0001$) in *AtiMutrata*, *AtiPipasa*, *AtiKshudha* & *Dourbalya*.
- Extremely statistically significant results ($P<0.0001$) was also seen in levels of FBS, PLBS & HbA1c level.
- No major hazardous side effects are noticed during the present study. So, it can be said to be a safer drug.
- During follow up study, some patients complained of increase in grade of symptoms after discontinuation of therapy. It shows that therapy should be administered for longer duration & then analysis should be done.

“Prevention is better than cure”-As the disease *Madhumeha* (diabetes mellitus type-II) is mainly found in the patients having irregular food & sleep habits, stress etc. By following healthy regimens like *Dincharya*, *Ratricharya* and *Ritucharya* etc, explained in the classics the disease can be prevented.

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